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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/424,521	02/15/2000	PETER E. NIELSEN	ISIS-3070	8096

7590

04/03/2002

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EXAMINER

WANG, ANDREW J

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 04/03/2002

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/424,521

Applicant(s)

NIELSEN, PETER E.

Examiner

Andrew Wang

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-18,20,21,23-27,31-34,38-41,45-48 and 52 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 15-18,20,21,23-27,31-34,38-41,45-48 and 52 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 26 February 2002 has been entered. Furthermore, applicant's amendments/reply filed on 19 September 2001 and 4 December 2001 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 15-18, 23, 25-27, and 31 are rejected under 35 U.S.C. 102(a) as being anticipated by WO92/20702 ('702).

'702 discloses methods of modulating uptake of a peptide nucleic acid (pna) by derivatizing the backbone of a pna to include a lysine amino acid side-chain as well as an alkyl, lipid, or steroid moieties (pages 8-10). Further '702 teaches the particularly claimed R^H modifications that include OH, NH₂, and NHLysNH₂ (see examples).

Therefore, all of the limitations of the above claims have been anticipated by WO92/20702.

4. Claims 15-18, 20, 21, 23-27, 31-34, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO92/20702 ('702) in view of Renneisen et al.

The invention of the above claims is drawn to a method of modulating cellular uptake of a pna, incorporated into a liposome, by derivatizing the pna backbone with a lysine side-chain as conjugatingn alkyl, lipid, or steroid moieties to said lysine side-chain.

'702 is relied upon as discussed above. '702 does not teach the use of a liposome.

Renneisen et al. teach the use of liposomes to deliver encapsulated oligos to cells.

It would have been obvious to one of ordinary skill in the art to use the liposomes as taught by Renneisen et al. to encapsulate the pna oligos as taught by '702 since '702 clearly contemplates the use various carriers to deliver the taught pna oligo. One would have been motivated to use liposomes, as disclosed by Renneisen et al., as a carrier for the pna oligo since Renneisen et al. clearly teach that liposomes were effective carriers for oligos such that cellular delivery could be achieved.

Therefore, as discussed above, the invention of the above claims would hve been prima facie obvious in over WO92/20702 in view of Renneisen et al. without evidence to the contrary.

5. Claims 39-41, 45-48, and 52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way

as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the same reasons of record as set forth in the Office action mailed 2 August 2000.

Applicant's arguments filed 24 September 2001 have been fully considered but they are not persuasive. Applicants assert that the amendment changing the language of claims 39 and 46 obviates the rejection of record but contrary to applicants assertion, changing the phrase "treating an animal" to "modulating gene expression in an animal" still reads on therapy and thus, does not obviate the instant rejection.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-18, 20, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The method steps of the instant claims do not relate back to the preamble which states a method of modulating cellular uptake and distribution of a peptide nucleic acid. The instantly recited method steps only refers to methods of making a peptide nucleic acid.

7. Any rejections not repeated in this Office action is hereby withdrawn.

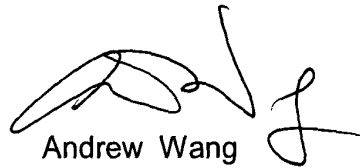
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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew Wang whose telephone number is 703-306-3217. The examiner can normally be reached on Monday thru Thursday, 6:30 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

AJW
March 28, 2002



Andrew Wang
Primary Examiner
Art Unit 1635